

§ 201.55

21 CFR Ch. I (4–1–02 Edition)

drug in ampules or vials, intended for injection, the declaration shall be considered to express the minimum quantity and the variation above the stated measure shall comply with the excess volume prescribed by the National Formulary or the U.S. Pharmacopeia for filling of ampules. In the case of a solid drug in ampules or vials, the declaration shall be considered to express the accurate net weight. Variations shall comply with the limitations provided in the U.S. Pharmacopeia or the National Formulary.

(h) A drug shall be exempt from compliance with the net quantity declaration required by this section if it is an ointment labeled “sample”, “physician’s sample”, or a substantially similar statement and the contents of the package do not exceed 8 grams.

§ 201.55 Statement of dosage.

Section 201.100(b)(2) requires that labels for prescription drugs bear a statement of the recommended or usual dosage. Since the dosage for some prescription drugs varies within extremely wide limits, depending upon the conditions being treated, it may not be possible in all cases to present an informative or useful statement of the recommended or usual dosage in the space available on the label or carton of the package. It is the view of the Food and Drug Administration that when such a situation prevails, compliance with this requirement would be met by a statement such as “See package insert for dosage information”, where the detailed information is contained in such insert. However, if an informative, realistic, recommended or usual dosage can readily be set forth on the label, it should appear thereon.

§ 201.56 General requirements on content and format of labeling for human prescription drugs.

Prescription drug labeling described in § 201.100(d) shall contain the information in the format required by § 201.57 and shall meet the following general requirements:

(a) The labeling shall contain a summary of the essential scientific information needed for the safe and effective use of the drug.

(b) The labeling shall be informative and accurate and neither promotional in tone nor false or misleading in any particular.

(c) The labeling shall be based whenever possible on data derived from human experience. No implied claims or suggestions of drug use may be made if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness. Conclusions based on animal data but necessary for safe and effective use of the drug in humans shall be identified as such and included with human data in the appropriate section of the labeling, headings for which are listed in paragraph (d) of this section.

(d)(1) The labeling shall contain specific information required under § 201.57 under the following section headings and in the following order:

Description.
Clinical Pharmacology.
Indications and Usage.
Contraindications.
Warnings.
Precautions.
Adverse Reactions.
Drug Abuse and Dependence.
Overdosage.
Dosage and Administration.
How Supplied.

(2) The labeling may contain the following additional section headings if appropriate and if in compliance with § 201.57 (l) and (m):

Animal Pharmacology and/or Animal Toxicology.
Clinical Studies.
References.

(3) The labeling may omit any section or subsection of the labeling format if clearly inapplicable.

(4) The labeling may contain a “Product Title” section preceding the “Description” section and containing only the information required by § 201.57(a)(1)(i), (ii), (iii), and (iv) and § 201.100(e). The information required by § 201.57(a)(1)(i), (ii), (iii), and (iv) shall appear in the “Description” section of the labeling, whether or not it also appears in a “Product Title.”

(e) The labeling shall contain the date of the most recent revision of the labeling, identified as such, placed